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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/799,528

03/13/2004

David J. Paul

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EXAMINER

MAI, HAO D

ART UNIT

PAPER NUMBER

3732

MAIL DATE

DELIVERY MODE

06/26/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/799,528	<b>Applicant(s)</b> PAUL ET AL.	
	<b>Examiner</b> HAO D. MAI	<b>Art Unit</b> 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 128-137 and 145-150 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 128-137 and 145-150 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed on 04/20/2009 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/31/2009 has been entered.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claim 147 is rejected under 35 U.S.C. 102(a) as being anticipated by Taylor et al. (6,036,641).**

Taylor et al. disclose a device (refer to Fig. 9A) capable of providing additional stabilization to tissue already in contact with a primary stabilization member, the device comprising: at least one tissue contact member 1 capable of being placed on the tissue in an area bounded by primary tissue contact members, said at least one tissue contact member 1 comprises a base member having a central opening (between the legs of the U-shape), said opening is capable of allowing access to a target site on the tissue. The base member 1 further has an outer perimeter portion (area towards the handle) that cants upward from a bottom surface of said base member located interiorly of said outer perimeter portion, such that Figure the bottom surface located interiorly is capable of contacting the tissue while at least the outer

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perimeter portion (towards the handle) cants upward and capable of contacting the primary stabilization member. The device further comprises at least one second opening 47 through a portion of said contact member that is not on said bottom surface, the second opening 47 is capable of delivering positive pressure there through (column 17 lines 30-42). The device also has a connecting member (handle) extending from the contact member and is capable being hand held or fixed to a relatively immovable object.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claims 128-133, 145, and 148-149, are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. (6,036,641).**

Regarding claims 128, Taylor et al. disclose a device 1 (refer to Fig. 9A) capable of providing additional stabilization to tissue already in contact with a primary stabilization member, the device comprising: a single, substantially rigid tissue contact member 1 formed as a unitary U-shaped loop capable of being placed on the tissue; and a connecting member/handle integrally formed with and extending from the tissue contact member and capable of being hand held or fixed to a relatively immovable object (Fig. 9A). The bottom surface of the contact member includes a contact surface that declines angularly in a radial direction from a periphery of said loop towards an opening (between the legs of the U-shaped loop) in the middle of said loop, i.e. the outer periphery that contains lumen 48/47 is shown to be thicker than the area toward to the center.

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Taylor et al. disclose the invention substantially as claimed except for the loop being continuous. However, such continuous loop shape is well known in the surgical field. For example, in the embodiments of Figures 7B and 8, Taylor et al. show a contact member in the shape of a continuous loop. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the U-shaped loop of Figure 9A to be a continuous loop in order to establish a more stable contact between the contact member and the tissue. Furthermore, such modification is merely a change in shape that is well within the skill of a person in the art. MPEP § 2144.04.

As to claims 129, the embodiments of Figure 9A, 7B, and 8, each or the combination thereof has a base with central opening there through, capable of allowing access to a target site on the tissue. As to claims 130-131, such substantially oval-shaped, if not explicitly disclosed by Taylor et al., would have been an obvious design choice well within the skill of a person in the art. MPEP § 2144.04. As to claims 132-133, Figure 9A shows the base member having a substantially hollow interior (defined by lumen 48 extending through the base member as shown in Fig. 9A) capable of developing a negative or positive pressure therein; and said lumen 48 is in fluid communication with said base member (column 17; lines 30-42).

Regarding claims 145 and 148-149, Taylor et al. disclose all the claimed elements as detailed above with respect to claims 128-133.

**6. Claim 134-137, 146, and 150, are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. (6,036,641) in view of Borst et al. (5,836,311).**

As to claim 134, Taylor et al. disclose the invention substantially as claimed including openings 47 being fluidly connecting with said substantially hollow interior (lumen 48) and capable of applying a negative pressure to the tissue (column 17 lines 30-42). However, Taylor et al. fail to disclose such openings being at the bottom surface of the contact member. Borst et

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al. disclose a base member 81 having substantially hollow interior and integral suction ports/openings 82 at the bottom surface thereof; the hollow interior and the suction ports/openings 82 are capable of developing and applying a negative pressure to the tissue (Fig. 13; column 7 lines 18-41). Figure 13 also shows a connecting member/handle being fluidly connected to the hollow interior of base 81 and is capable of being connected to a source of negative pressure (column 7 lines 18-35). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Taylor et al. by placing such suction ports/openings at the bottom surface in order to provide a suction mechanism that suck onto or seal with the tissues, providing a more effective stabilization of the heart as explicitly taught by Borst et al.

As to claims 135-137, Taylor et al. in Figure 9A disclose the base member having openings 47 through an upper surface thereof (Fig. 9A column 17 lines 40-42), and the openings 47 being connected to two different lumens 48. However, Taylor et al. fail to teach a source of pressure that is independent from a pressure in the hollow interior of said base member. Borst et al. disclose two separate independent suction sources (column 7 lines 29-34). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Taylor et al. with two separate independent suction sources so that if one suction source were to lose contact with tissue, the other could still maintain capture as explicitly taught by Borst et al. (column 7 lines 29-34). Alternatively, one (negative) suction source can be used for adhering the contact member to the tissue as taught by Borst et al.; the other (negative or positive) suction source can be used for maintaining the surgical site clear and dry as taught by Taylor et al.

Regarding claims 146 and 150, Taylor et al. in combination with Borst et al. disclose all the claimed elements as detailed above.

### ***Response to Arguments***

7. Applicant's arguments regarding the amended claims have been fully considered but they are not persuasive and/or moot in view of the new ground(s) of rejection. Applicant's remarks are held to be responded to the above ground(s) of rejection.

In the arguments, Applicant relies mostly on the functional language recited in the claims such as "for providing additional stabilization to tissue already in contact with a primary stabilization member" (in the preamble of claims 129, 145-150). Once again, the Examiner notes that such claim language is functional or intended use and does not convey any positive structural limitation. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham, 2 USPQ2d 1647 (1987)*. If the prior art structure is capable of performing the intended use, then it meets the claim. *In re Hutchison, 69 USPQ 138*.

### ***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAO D. MAI whose telephone number is (571)270-3002. The examiner can normally be reached on Monday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be reached on (571) 272-4964. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/Hao D Mai/  
Examiner, Art Unit 3732**

**/Cris L. Rodriguez/  
Supervisory Patent Examiner, Art Unit 3732**